

Notice of Allowability

Application No.

10/665,361

Examiner

ANAND U. DESAI

Applicant(s)

BOYLE ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to May 9, 2008.
2. ☒ The allowed claim(s) is/are 1-5,8,12,15-17,20,23,26,31,34,37,40,54,206,207 and 210-217.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application
- ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
- ☒ Examiner's Amendment/Comment
- ☐ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

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DETAILED ACTION

1. This office action is in response to the amendment filed on May 9, 2008. Claims 43, 205, 208, 209, and 218 have been cancelled.
2. Claims 1-5, 8, 12, 15-17, 20, 23, 26, 31, 34, 37, 40, 54, 206, 207, and 210-217 are currently pending and are under examination.

Withdrawal of Rejections

3. The rejection of claims 1-5, 8, 12, 15-17, 20, 23, 26, 31, 34, 37, 40, 54, and 211-217 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the amendment to describe the growth hormone antagonist as B-2036.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Nicholas I. Slepchuk, Jr. on August 1, 2008.

Examiner's amendment to the claims:

2. (Currently Amended) The process of claim 1 further comprising the step ~~(a1)~~ of pegylating unpegylated or a partially pegylated form of the protein, or pegylating both to provide said pegylated protein isoforms.

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3. (Currently Amended) The process of claim 2 wherein said pegylating step ~~(a1)~~ comprises pegylating with free PEG selected from ~~from~~ the group consisting of PEG-N-hydroxysuccinimide-5K ~~hydroxysuccinimide-5K~~, PEG-succinimidyl carbonate-5K, PEG-succinimidyl-propionate-5K, PEG2-maleimide-40K (2 x 20K), PEG2-N-hydroxysuccinimide-40K (2 x 20K), and PEG2-aldehyde-40K (2 x 20K).

8. (Currently Amended) The process of claim 2 wherein said pegylating step ~~(a1)~~ is conducted at pegylating pH from about 3 to about 10.

15. (Currently Amended) The ~~the~~ process of claim 2 wherein said said pegylation step ~~(a1)~~ is conducted at a pegylating temperature from about 18 to about 25 ° C.

17. (Currently Amended) The ~~the~~ process of claim 2 further comprising an optional hydrophobic interaction chromatography (HIC) step ~~(a2)~~ selecting said pegylated protein by HIC using an HIC resin.

23. (Currently Amended) The process of claim 17 wherein said HIC step ~~(a2)~~ is conducted at HIC temperature from about 10 to about 40 ° C.

26. (Currently Amended) The process of claim 17 further comprising a ultrafiltering/diafiltering (UF/DF#3) step, ~~(a3)~~ ultrafiltering/diafiltering (UF/DF#3) of an eluent from said HIC step ~~(a2)~~.

31. (Currently Amended) The process of claim 1 wherein said step (b) further comprises a step ~~(b1)~~ of loading said pegylated protein including any impurity and any aggregate thereof on said anion exchange (AEX) resin to provide loaded pegylated protein.

34. (Currently Amended) The process of claim 31 wherein ~~said~~ the loading step ~~(b1)~~ is conducted at an AEX loading conductivity of less than or equal to about 10 mS/cm.

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37. (Currently Amended) The process of claim 31 wherein ~~said~~ the loading step (b1) is conducted at a loading pH from about 5 to about 10.

40 (Currently Amended) The process of claim 31 wherein ~~said~~ the loading step (b1) is conducted at an AEX load of pegylated protein including any impurity or said aggregate thereof of less than or equal to about 10 g protein/L of packed bed-volume of AEX resin.

In claim 54 please remove the "." after the word "by" on the third line of the claim.

Allowable Subject Matter

5. Claims 1-5, 8, 12, 15-17, 20, 23, 26, 31, 34, 37, 40, 54, 206, 207, and 210-217 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 1, 2008

/Anand U Desai, Ph.D./

Patent Examiner, Art Unit 1656